**REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment are respectfully requested. The present response replies to the Office Action dated June 22, 2010. Claims 1, 2, 4-7, 9-28, 30, and 32-37 are pending in the present application. Claims 11-28, 30, and 32 were previously withdrawn. Claims 2 and 7 have been cancelled and claims 38 and 39 added herein. Claim 37 has also been amended to correct a typographic error and not to avoid any prior art. In the Office Action, the Examiner rejected claims 1, 2, 4-7, 9, 10, and 33-37 on various grounds. In view of the amendments and following remarks, favorable consideration and allowance of the Application is respectfully requested.

*35 U.S.C. §112 Rejections*

The Examiner rejected claims 2 and 7 under 35 U.S.C. §112, first and second paragraphs. Claims 2 and 7 have been cancelled herein to expedite prosecution and not to avoid any prior art.

*Double Patenting*

The Examiner noted the provisional rejection of claims 1, 2, 4-7, 9, 10, and 33-37 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending application 10/827,817. Because the copending claims of application 10/827,817 may change during prosecution, the Applicant will consider filing a terminal disclaimer when the present application is otherwise in condition for allowance.

*35 U.S.C. §103 Rejections*

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

**A. Claims 1, 2, 4-7, 9, 10, 33, 36, and 37 were rejected under 35 U.S.C. §103(a) as being anticipated by U.S. Patent No. 5,356,433 to Rowland, *et al.* (the *Rowland* patent) in view of U.S. Patent No. 6,240,616 to Yan (the *Yan* patent).**

The Applicant respectfully asserts that the *Rowland* patent and the *Yan* patent, alone or in combination, fail to disclose, teach, or suggest:

a stent delivery system including a coating disposed on the silane layer, the coating being a non-biologically active polymer, as recited in claim 1;

a coated stent including a coating disposed on the silane layer, the coating being a non-biologically active polymer, as recited in claim 6; or

a coated stent including a polymer coating disposed on the amino silane layer, the polymer coating being a non-biologically active polymer including a therapeutic agent, as recited in claim 33.

At most, the *Rowland* patent discloses covalently linking an organosilane having amine reactive sites with the surface of the metallic member, and covalently linking a biologically active agent to the organosilane coating. *See* Abstract; column 5, lines 22, 23. As noted by the Examiner on page 5 of the Office Action dated June 22, 2010, the *Rowland* patent does not disclose a coating disposed on the silane layer, the coating being a non-biologically active polymer.

At most, the *Yan* patent discloses that the membrane [*sic*] is bioabsorbable, but no therapeutic agent is loaded into the polymer. The coating 100 dissolves after implantation and this delays the time that a therapeutic agent is released into the vasculature of a patient. The thickness of the coating as well as the rate at which the coating is bioabsorbed determines the length of time that the stent is mounted into the vascular before a therapeutic agent is delivered from the pores of the stent. *See* column 9, lines 22-29. On page 5 of the Office Action dated June 22, 2010, the Examiner asserted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rowland such that a non-biologically active polymer layer including PCL was disposed over the silane layer to control the release rate of the biologically active agents attached to the amino-silane layer. However, this combination of the *Rowland* patent and the *Yan* patent is not the same as the claimed invention in which a coating of non-biologically active polymer is disposed on the silane layer, which is disposed on the stent. The Applicant's invention as claimed does not

include any biologically active agent attached to the amino-silane layer, radially interior from the coating, or within the coating itself, so there is no biologically active agent having a release rate to be regulated. Thus, the combination of the *Rowland* patent and the *Yan* patent results in a different device than the Applicant's invention as claimed.

In addition, the suggested modification changes the principle of operation of the *Rowland* patent, which renders metal surfaces of medical devices biocompatible by providing a biologically active agent on the outer surface. The biocompatible metal surfaces include an amino-functional organosilane which is covalently linked to metal oxides on the metal surface of the device while covalently linking a biologically active agent thereto and thereby to a silane-treated metal surface. This surface has biocompatibility characteristics while simultaneously presenting a surface which encourages endothelialization upon implantation within a blood vessel and the like. *See* column 1, lines 9-21. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *See* MPEP 2143.01, VI. The suggested modification defeats the principle of operation of the *Rowland* patent by interposing a polymer coating over the biologically active agent located on the outer surface for biocompatibility. The *Rowland* patent teaches away from a polymer outer surface because polymeric surfaces and metallic surfaces each pose different problems which must be overcome in order to provide a polymeric or metallic surface that is suitable for implantation and/or extended-time residence within the body. *See* column 1, lines 45-49.

Claims 4, 5, and 36; and claims 9, 10, and 37 depend directly from independent claims 1 and 6, respectively. Therefore, the dependent claims include all the elements and limitations of their respective independent claims. The Applicant respectfully submits that dependent claims 4, 5, 9, 10, 36, and 37 are allowable over the *Rowland* patent and the *Yan* patent for at least the same reasons as set forth above with respect to their respective independent claims.

Withdrawal of the rejection of claims 1, 4-6, 9, 10, 33, 36, and 37 under 35 U.S.C. §103(a) as being anticipated by the *Rowland* patent and the *Yan* patent is respectfully requested.

**B. Claims 34 and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Rowland* patent and the *Yan* patent in view of U.S. Patent No. 4,539,061 to Sagiv (the *Sagiv* patent)**

The Applicant respectfully asserts that the *Rowland* patent, the *Yan* patent, and the *Sagiv* patent, alone or in combination, fail to disclose, teach or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). As discussed in Section A above, the Applicant respectfully asserts that the *Rowland* patent and the *Yan* patent fail to disclose:

> a stent delivery system including a coating disposed on the silane layer, the coating being a non-biologically active polymer, as recited in claim 1;
>
> a coated stent including a coating disposed on the silane layer, the coating being a non-biologically active polymer, as recited in claim 6; or
>
> a coated stent including a polymer coating disposed on the amino silane layer, the polymer coating being a non-biologically active polymer including a therapeutic agent, as recited in claim 33.

The *Sagiv* patent also fails to disclose these limitations.

Claims 34 and 35 depend directly from independent claims 1 and 6, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claims 34 and 35 are allowable over the *Rowland* patent, the *Yan* patent, and the *Sagiv* patent for at least the same reasons as set forth above for their respective independent claims.

In addition, the *Sagiv* patent fails to disclose a thickness of the silane layer being 8-10 monolayers as claimed. At most, the *Sagiv* patent discloses a multilayer of up to a maximum of four monolayers. *See* column 10, line 63; column 11, line 49. Although the *Sagiv* patent speculates that films of any desired number of layers and thickness are possible, the results of the *Sagiv* patent are limited to four monolayers. Thus, the 8-10 monolayers of the Applicant's invention is a surprising and unexpected result in view of the four monolayers of the *Sagiv* patent.

Withdrawal of the rejection of claims 34 and 35 under 35 U.S.C. §103(a) as being unpatentable over the *Rowland* patent, the *Yan* patent, and the *Sagiv* patent is respectfully requested.

*New Claims*

Claims 38 and 39 have been added herein to more particularly point out and distinctly claim the Applicant's invention. Claims 38 and 39 are allowable over the cited references for at least the reasons discussed above for their respective independent claims 1 and 6. No new matter has been added with the inclusion of claims 38 and 39, which are supported in the specification at least on page 11.

*Conclusion*

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

/Anthony A Sheldon/
Anthony A. Sheldon
Registration No. 47,078
Attorney for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420